510(k) SUMMARY

510(k) Notification K062192

GENERAL INFORMATION

MAY 24 2007

Applicant:
Ostial Solutions, LLC
1111 Short Road
Kalamazoo, MI 49008
Phone: 269-383-3797
FAX: 269-383-3714

Contact Person:
Michael J. Billig
Regulatory Consultant
Experien Group, LLC
155 Moffett Park Dr., Suite A-210
Sunnyvale, CA 94089
Phone: 408-400-0856
FAX: 408-400-0865
Email: mjb@experiengroup.com

Date of Submission:
July 28, 2006

DEVICE INFORMATION

Classification:
Class II - Standards

Trade Name:
Ostial Pro Stent Positioning System

Common/Classification Name/Product Code:
Product Code: DQX
Device Classification: Catheter Guidewire
Regulation Number: 870.1330

PREDICATE DEVICES

- Cordis® Corporation, ATW™ Marker Wire Steerable Guidewire, K994358
- Lake Region Manufacturing, Inc., Coronary, Peripheral and Renal Steerable Hydrophilic Guidewire, K042338
- EV3® Inc., Nitrex® Guidewire, K031864
- BioSphere Medical, Inc., Sequitor™ Steerable Guidewire, K061171

INTENDED USE

The Ostial Pro Stent Positioning System is intended for use in aorta-ostial procedures to introduce and position catheters, stents and other interventional devices within the coronary and peripheral vasculature. In addition, the Ostial Pro Stent Positioning System is intended to facilitate the alignment of interventional devices and function as an alignment tool.

PRODUCT DESCRIPTION

The Ostial Pro Stent Positioning System is a medical grade, disposable guidewire system. The Ostial Pro Stent Positioning System will be used by interventional cardiologists and interventional radiologists to ensure precise stent implantation in aorta-ostial procedures. The product will be used in coronary and renal stenting procedures. The product is provided sterile and intended for single use.

This finished product will be compatible with 6, 7 and 8 French catheters.

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate devices are substantially equivalent to the proposed indications for use for the Ostial Pro Stent Positioning System. The technological characteristics for the Ostial Pro Stent Positioning System are also substantially equivalent to the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the Ostial Pro Stent Positioning System is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

The safety of the Ostial Pro Stent Positioning System was evaluated through design verification testing, biocompatibility testing and preclinical animal testing. The collective results have demonstrated that the Ostial Pro Stent Positioning System is safe and is substantially equivalent to the respective predicate devices with regard to safety and efficacy. Any differences in technological characteristics between the Ostial Pro Stent Positioning System and the predicate devices do not raise any new issues of safety or efficacy.

SUMMARY

The Ostial Pro Stent Positioning System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2007

Ostial Solutions, LLC
c/o Mr. Michael J Billig
Regulatory Consultant
1111 Short Road
Kalamazoo, MI 49008

Re: K062192
Ostial Pro Stent Positioning System
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: II (two)
Product Code: DQX
Dated: May 14, 2007
Received: May 15, 2007

Dear Mr. Billig:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OSTIAL SOLUTIONS, LLC
1111 SHORT ROAD
KALAMAZOO, MI 49008

INDICATIONS FOR USE

510(k) Number (if known): K062192

Device Name: Ostial Pro Stent Positioning System

Indications for Use:

The Ostial Pro Stent Positioning System is intended for use in aorta-ostial procedures to introduce and position stents and other interventional devices within the coronary and peripheral vasculature. In addition, the Ostial Pro Stent Positioning System is intended to facilitate the alignment of interventional devices and function as an alignment tool.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susana R. Cochran
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062192